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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,061	05/19/2000	STEPHAN R. TARGAN	P-PM 4097	1578

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/575,061	TARGAN ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *NONE*.

   Claim(s) objected to: *NONE*.

   Claim(s) rejected: *1-7*.

   Claim(s) withdrawn from consideration: *8-11*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

10/19/04

ADVISORY ACTION

Amendment Entry

1. Applicant's response filed 9/16/04 is acknowledged. Claims 1-11 are pending. Claims 1-7 are remain under examination.

Restriction Requirement

2. Applicant requests reconsideration and withdrawal of the restriction requirement because restricted claims 8 and 10 both depend from claim 2 which is currently under examination. Applicant contends that while claim 2 is directed to a method of diagnosing Crohn's disease by determining the presence or absence of IgA anti-OmpC antibodies as a marker, restricted claim 8 depends from claim 2 and only further including detecting the presence or absence of another marker which is IgA anti-I2 polypeptide antibodies, and claim 9 also depends from claim 2 and only further including detecting the presence or absence of another marker which is IgA anti-ASCA. Applicant then concludes that since all the restricted groups include the detection of the presence of absence of IgA anti-OmpC antibodies, a search for claim 2 would encompass the subject matters of claims 8 and 10, without requiring undue burden on the Examiner.

In response, while searches would be expected to overlap or encompassing as suggested by Applicant, there is no reason to expect the searches to be coextensive because the claims recite specific, separate, and distinct additional diagnostic markers

for diagnosing Crohn's disease; thus, rendering the claims independent from the other for having different structural requirements for each invention. Contrary to Applicant's contention, a search for "IgA anti-OmpC antibodies", in relation to "Crohn's disease", may result to relevant literature possibly including a discussion of IgA anti-I2 polypeptide antibodies and/or IgA ant-ASCA, but not necessarily so, unless extensive search for each of "IgA anti-I2 polypeptide antibodies" and/or "IgA anti-ASCA" in relation to both of "IgA anti-OmpC antibodies" and "Crohn's disease" is also executed and reviewed for relevancy, novelty, and obviousness in relation to the limitations identified by the claimed invention. Applicant's argument that examination of all the claims would not pose serious undue burden to the examiner, therefore, is without merit. Accordingly, the restriction requirement is being maintained.

3. Applicant requests a "second-eye-review" as implemented under the Restriction Practice Action Plan.

In response, the "second-eye-review" under the Restriction Practice Action Plan has been implemented only for select groups or art units in the patent corps. However, it has not been mandated as patent examination policy. Alternatively, Applicant has the option of petitioning for the withdrawal or modification of the restriction requirement to the Office of Petitions.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-7 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for all of IgA outer membrane protein C (OmpC) antibody, anti-Saccharomyces antibody (ASCA), I-2 polypeptide antibody (I-2 antibody), and perinuclear anti-neutrophil antibodies (pANCA) as cumulative diagnostic markers for use in a method for diagnosing the presence of Crohn's disease, does not reasonably provide enablement for using only solely IgA anti-OmpC antibody as an independent diagnostic marker for diagnosing the presence of Crohn's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection is being maintained for reasons of record.

Response to Arguments

5. Applicant's arguments filed 9/16/04 have been fully considered but they are not persuasive.

A) Applicant argues that the specification is enabled in teaching detection of Crohn's disease based on detection of IgA anti-OmpC antibodies alone. Applicant specifically contends that as shown in Table 2, IgA OmpC reactivity itself detected 55% of patients having Crohn's disease and as shown in Figure 4, IgA anti-Ompc antibodies were present in 56% of patients having Crohn's disease, but in only 1 of 26 individuals without Crohn's disease. According to Applicant, the results shown in Table 2 and

Figure 4 show that anti-OmpC antibodies are present in a large subset of patients with Crohn's disease and can thus, serve to diagnose Crohn's disease where they are present.

In response, the fact that the presence of IgA anti-OmpC antibody occurs in subjects with Crohn's disease more often than not (56%), and only 1 out of 26 subjects without Crohn's disease test positive for IgA anti-OmpC antibodies, only provide that the presence of IgA anti-OmpC antibodies is associated to or at best, predictive of Crohn's disease, as concurred by Applicant in his reply. The subjects tested are not representative of a general population, and the number of subjects tested in order to determine that IgA anti-OmpC antibody can be used in a claimed diagnostic method for Crohn's disease is not sufficient to establish adequate correlation between the presence of IgA anti-OmpC antibodies and the diagnosis of Crohn's disease. The specification fails to define that a nexus between the presence of anti-OmpC antibodies in a general population and Crohn's disease exists, so as to render the claimed antibodies as being diagnostic markers for Crohn's disease, which is encompassed by the claimed invention. Absent evidentiary showing that a correlation exists between the presence of IgA anti-OmpC antibody and actual diagnosis of Crohn's disease in 55% of any given population, the specification is not enabled for the claimed invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571)

272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
October 19, 2004

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
10/22/04